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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,968	09/19/2000	Ping Yip	24736-2049	4499

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HELLER EHRMAN LLP
4350 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122-1246

EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,968

Applicant(s)

YIP, PING

Examiner

Karlheinz R. Skowronek

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-91 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

The examiner of record has changed. Please direct all further correspondence to Karlheinz R. Skowronek whose telephone number is (571) 272-9047.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06 March 2006 has been entered.

Claim Status

Claims 1-45 have been canceled. It is stated in the amendment that claims 46-92 are newly added, however only claims 46-91 are present.

Claims 46-91 are pending.

Claims 46-91 are being examined.

Claim objections

Claim 52 is objected to because of the following informalities: It appears that the part of the claim is missing or has been lost to the margin. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The term “probable peak” in claims 46, 84, 86 and 87 is unclear. The term “probable peak” is not defined by the specification nor does the claim reflect the meaning of the term. What is a probable peak? How is it related to a “putative peak”? Claims 47-83 also rejected because they depend from claim 46, and thus contain the above issues due to said dependence. Claim 85 also rejected because it depends from claim 84, and thus contain the above issues due to said dependence. Claims 88-91 also rejected because they depend from claim 87, and thus contain the above issues due to said dependence.

b. The term “address” in claims 63-65 is unclear. The term “address” is not defined by the specification nor does the claim reflect the meaning of the term.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

Claims 46-86 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA samples, does not reasonably provide enablement for any biological sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The claims are drawn to a method of identifying a component in a biological sample. The breadth of the claims encompasses any biological sample, processed or non-processed, protein, nucleic, small chemical, metabolite, etc.

Given a theoretical spectrum, one of ordinary skill in the art would be able to determine if the theoretical spectrum correlates to the actual, obtained spectrum for a defined sample. The art teaches the identification of protein components of a biological solution via the comparison of the experimentally determined masses to theoretical masses based on protein and DNA database data (Gevaert et al. Electrophoresis, Vol. 21, p. 1145-1154, 2000). For example, the protein components of a sample are first purified and then chemically or proteolytically digested to produce a spectrum that is used as a characteristic "fingerprint". The "fingerprint" is then compared to a theoretical "fingerprint" to determine the protein or proteins that are constituents of the sample. A similar method is used to identify DNA sequences by mass spectroscopy. The art is silent on *de novo* peak assignment, i.e. assigning the identity of a peak without database correlation (as described above). The art teaches whole cells can be analyzed by mass spectroscopy, however the mass spectra obtained from whole cells are complex and irreproducible (Wilkes et al., Rapid Communications in Mass Spectroscopy, Vol. 20, p. 1595-1603, 2006). The art teaches that the technique of MALDI-TOF mass spectroscopy provides measurements of mass within 0.01% accuracy in a few seconds, however has difficulty differentiating between isomer such as leucine and isoleucine or glutamine and lysine (Bonk et al., Neuroscientist, Vol. 7,

Iss. 1, p. 6-12, 2001). Thus the intrinsic limitation of mass spectroscopy is in differentiating between different compounds of identical masses.

The specification teaches the analysis of spectra derived from processed DNA samples with known components. The specification does not provide the guidance to identify components from any biological sample, processed or unprocessed, such as whole cells. Biological samples that are complex mixtures of many types of components have the added complexity of potential effects due to the interactions between components in the mixture. These interactions can cause the masses to differ from the masses predicted by information from DNA and protein databases (Lay, Mass Spectrometry Reviews, Vol. 20, p. 172-194, 2001). Complex mixture biological samples can also contain components that have overlapping, identical masses. One of ordinary skill in the art would not know how to differentiate between different chemical species of identical mass. The specification does not provide the guidance that would be necessary for one of ordinary skill in the art to use the invention to identify components with identical masses. The specification also fails to provide an example of the identification of components in any sample. The claims, drawn to identifying the components of any biological sample, do not have the support in the specification for identifying the components of any sample. Thus, undue experimentation would be required of one of ordinary skill in the art use the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1631

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 91 is rejected under 35 U.S.C. 102(b) as being unpatentable over Shew (USPN 5,436,447).

The claim is drawn to a system for identifying a component in a biological sample via an instrument and a computing device.

The reference teaches an instrument and computing device. The claim language “for receiving ... and performing the steps...” is considered as an intended use limitation and as such is not given patentable weight in determining the patentability of the system. Nevertheless, the reference does teach the generation of a corrected data set with putative peaks and defining the positions of expected peaks (col. 6, lines 19-25); shifting the corrected data set (col. 15, lines 56-58); calculating the probability the putative peaks in the shifted data are actual peaks (col. 16, 43-45); comparing the probabilities to generate a calling ratio and use the ratio to determine the identity of the component of the sample (fig 9).

No claims allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

